Hospital Equipment (36740462280002) One lot consisting of 2ea monitor Olympus OEV191H-u 19 in LCD video, 1ea EV-C60 Exera Olympus EU-C60 Exera CLA video system, 2ea CV180 Evis Olympus ExeraII video System, 2ea WM-WP1 keymed cart video procedure,1 ea Olympus CLV 180 scope light source, 1ea Olympus CLV 160 scope light source, 2ea Olympus OEP4 color printer medical, 1ea HP desk jet 6940 printer color, 2ea misc carts supply. Purchaser is responsible for all packing, loading, shipping and removal of all equipment in a timely manner. POC is Reynaldo Castillo @254-743-2131. ** Winning bidder required to complete and submit the attached "71QSCI16483010 Medical Devices SOI.pdf" prior to removal. E-mail to mark.maxwell@gsa.gov with a Cc to: Reynaldo.castillo@va.gov is the preferred method of submission**.

MEDICAL DEVICES. Purchasers of all medical equipment listed in the Invitation for Bid (IFB) shall certify and assure in writing that such item will b e used or resold only under the conditions specified below:

Medical device items are subject to the laws and regulations administered by the Food and Drug Administration (FDA). Provisions of the governing statute, the Federal Food, Drug and Cosmetic Act appear in 21 U.S.C. 331, ET. Seq. In summary, the Act prohibits the movement in interstate commerce of medical devices that are misbranded or adulterated. The Act authorizes FDA to initiate criminal enforcement proceedings against companies and/or individuals responsible for violations of its provisions. Moreover, the Act authorizes FDA to initiate civil proceedings to seize, or enjoin the distribution of such items.

It shall, also, be the responsibility of all purchasers to comply with local, state, or other applicable laws.

The following certificate, to be a separate attachment to the Invitation for Bid, is required by FDA to purchase the medical device items identified in the Invitation.

I certify that I am a licensed practitioner and/or other person regularly and lawfully engaged in the manufacture and/or refurbishing of the medical device item identified in the IFB. I, also, certify that prior to sale or use of such a device, I will take assurance that such a device is not adulterated or misbranded within the meaning of those terms in the Federal Food Drug and Cosmetic Act (21 U.S.C., et Seq.).

_____ _____

Signature **Date**

Recognizing that Federal law places stringent restrictions on adulterated or misbranded medical devices (21 U.S.C. 331, et. Seq.), I certify that I either will sell or otherwise proffer the medical device item identified in the IFB to persons described in the above, or will not use this item(s) for their original or usual intended use, for any other medical use.

_____ _____

Signature **Date**

False or misleading statements may result in a fine of not more than $10,000 or imprisonment for not more than five (5) years, or both (18 U.S.C. 1001).